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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,090	10/23/2003	Shigeru Nemoto	KITO2.001DV5	8325
20995 7590 11/19/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER DESANTO, MATTHEW F	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 11/19/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/692,090

Applicant(s)

NEMOTO, SHIGERU

Examiner

Matthew F. DeSanto

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,10,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/28/07, 9/19/07, 7/11/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3, 9, 10, 12, 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a degree of roughness, the claim and specification does not reasonably provide enablement for a flange having a roughness of about No. 20-1500. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The examiner has not been able to find a standard of roughness, which causes a problem with the claims and specification since there is no way to figure out the scope of the claim and how to determine the roughness of an element that is between No. 20 to 1500 as expressed in terms of counts of sand paper. The problem that occurs is that counts of sand paper is determined by the average diameter size of the "sand" or grit in the paper, but the problem is that the claim in the instant invention never recites any element that has the specific diameter size in accordance with the counts of sandpaper. Thus the examiner doesn't want to limit the applicant to an average particle size since there are other ways to create roughness, but the specific doesn't give any way to determine the roughness that is created by these other ways. Therefore, one of ordinary skill has no way to

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determine roughness that is created by these other ways, unless they use the average diameter size of the particles.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1, 3, 9, 10, 12, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The claims are unclear since the term roughness is not a standard and counts of sandpaper have no specific roughness, only a specific average diameter of the particles or sand.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 9, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al. (USPN 5,407,431), in view of Ericson et al. (US Pub 20010014996 A1) and Skakoon et al. (USPN 4,804,368).

Botich et al. discloses a pre-filled syringe (Col. 11, lines 14-24) with a syringe barrel comprising a flange that has a front and rear surface, wherein the front surface is roughened (Col. 11, lines 14-24, see figure 1) "to provide a greater coefficient of

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friction". The grooves (83) have a regular patterned of roughness since each groove is roughened and the roughness has a convex and concave pitch over the front surface of the flange because of the valleys and ridges that are formed by the grooves (83).

Botich et al. fails to disclose "wherein the cross section of the roughened surface has a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper" and "wherein at least one of the front and rear surface is randomly roughened".

Ericson et al. discloses a wedge clamp type termination for elevator tension members, but more importantly Ericson et al. teaches using sandblasting to raise the coefficient of friction of a surface (paragraph [0036]). Ericson et al. further teaches other methods of increasing the surface friction, which include etching, machining, knurling and other suitable equivalents.

Skakoon et al. discloses an infusion apparatus with a cylinder holder that includes a flange insertion groove that allows all different types of syringes to fit into the cylinder holder (Column 5, line 15-35).

Therefore, at the time of the invention it would have been obvious to use sandblasting as another means of roughening the front surface of the flange to create a greater coefficient of friction between the fingers and thumb because it is well known that there are many methods that can be used to increase surface friction as taught by Ericson et al. By using this method of increasing the coefficient of friction, the cross section of the roughened surface having a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper would be an obvious modification since the

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range lacks any criticality or special feature and thus such a range would have been obvious to one skilled in the art wishing for a particular roughness and friction.

The examiner would also like to note that by using sandblasting, it would cause random roughening because sand is being blasted into the object, thus causing the sand to be randomly placed into the object due to the force being exerted on the sand, thus creating a random pattern after each injection. This pattern can be controlled and follow a regular pattern if this method is used to form sections of roughened areas, thus creating a regular pattern from the roughened areas. Ericson et al. also teaches the formation of small ridges and valleys, which further supports the fact that the roughened section will have a convex and concave pitch (paragraph [0036]).

It would also be obvious to combine the teachings of Botich et al. and Ericson et al. with Skakoon et al., because Skakoon et al. discloses the benefit of using an automated infusion apparatus because the apparatus allows for a more precise and accurate way to infuse drugs and treatment into a patient (Column 2, line 48-55).

Response to Arguments

3. Applicant's arguments filed 8/27/07 have been fully considered but are not persuasive.

4. When the examiner was reading through the arguments it became clear that no standard of roughness existed in terms of count of sand paper, which led to the new 112 Rejections, since the claims are unclear if one of ordinary skill cannot determine the roughness from the specification and claims.

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5. The examiner maintains his rejection that combining the prior art will give you a device with a roughness equivalent to the claimed invention, since applicant's invention is made or can be made the same way.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
November 13, 2007



MATTHEW F. DESANTO
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